DEC 17 2013

2.6 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	December 13, 2013
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Mariela Cabarcas Regulatory Affairs Project Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 71246 Fax: 239/598.5508 Email: mcabarcas@arthrex.com
Trade Name	***Arthrex iBalance® TKA System***
Common Name	Knee Prosthesis
Product Code -Classification Name CFR	JWH 888.3560: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Predicate Device	K081127: Accin™ Total Knee System
Purpose of Submission	This **special 510(k)** premarket notification is intended to address the use of Gamma Irradiation sterilization method on the UHMWPE tibial bearing components of the ***Arthrex iBalance® TKA System.***
Device Description	The ***Arthrex iBalance® TKA System*** consists of femoral components, tibial tray, tibial bearing components and patellar components. All components are available in a range of sizes to fit varying anatomical requirements. Femoral components and tibial bearing components are available in both posteriorly stabilized (PS) and cruciate (CR) configurations. Femoral components are available in left and right versions and are designed to work with the Arthrex dome patella components. Femoral and tibial tray components are manufactured from Cobalt-Chromium Alloy conforming to ASTM F-75. Tibial bearing and patellar components are manufactured from UHMWPE conforming to ASTM F-648.

Intended Use	The ***Arthrex iBalance® TKA System*** is indicated for use in individuals undergoing surgery for: • Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis; • Post-traumatic loss of knee joint configuration and function • Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability; • Revisions of previous unsuccessful knee replacement or other procedure. Additional indications for posteriorly stabilized components: • Ligamentous instability requiring implant bearing surfaces with increased constraint; • Absent or non-functioning posterior cruciate ligament. These devices are single use only and are intended for implantation with bone cement.
Substantial Equivalence Summary	The ***Arthrex iBalance® TKA System*** is substantially equivalent to the predicate devices, in which the basic design features and intended uses are the same. Any differences between the Arthrex iBalance® TKA System and the predicates are considered minor and do not raise questions concerning safety and effectiveness. In the predicates, Gamma Irradiation sterilization is used for the Chromium Alloy components, and EtO sterilization is used for the UHMWPE components. In the proposed ***Arthrex iBalance® TKA System***, the UHMWPE components will also undergo Gamma Irradiation sterilization. Material properties of the gamma UHMWPE components have been fully characterized per ASTM F2565. Gamma sterilization had minimal effects on the mechanical properties of the PE, and the properties meet those listed in ASTM standard F648 for Type 2 PE. The mechanical testing data submitted demonstrates that there is no significant difference in mechanical strength between EtO and Gamma specimens. Based on the indication for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the ***Arthrex iBalance®***

	TKA System is substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 17, 2013

Arthrex, Incorporated
Ms. Mariela Cabarcas
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108

Re: K133342
Trade/Device Name: Arthrex iBalance® TKA System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: October 30, 2013
Received: November 4, 2013

Dear Ms. Cabarcas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.5 INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): K133342

Device Name: ***Arthrex iBalance® TKA System***

Indications For Use:

The ***Arthrex iBalance® TKA System*** is indicated for use in individuals undergoing surgery for:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis;
- Post-traumatic loss of knee joint configuration and function;
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Revisions of previous unsuccessful knee replacement or other procedure.

Additional indications for posteriorly stabilization components:

- Ligamentous instability requiring implant bearing surfaces with increased constraint;
- Absent or non-functioning posterior cruciate ligament.

These devices are single use only and are intended for implantation with bone cement.

Prescription Use _✓_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices